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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,288

Applicant(s)

SWANSON ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/19/09
11/18/03
2/21/03
1/22/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Applicant's election without traverse of the invention of Group I and the species of Figure 13 corresponding to claims 44-114 in the reply filed on January 17, 2006 is acknowledged.

It is noted that applicant has indicated that several of the claims have been copied (either exactly or substantially) from three issue patents in order to provoke an interference. All claims in this instant application are rejected under prior art. As such, no interference may be declared at this time. Additionally, the examiner notes that present claims 51 and 52 of the instant application have been denoted as corresponding to claim 1 of US Patent No. 6,117,101. However, claim 1 of the '101 patent clearly sets forth an ultrasonic ablation means, and the instant application contains no disclosure of the use of an ultrasonic ablation means. The examiner deems the claims of the '101 patent to be patentably distinct from the claims of the instant application and sees no reason to justify an interference between the instant application and the '101 patent in view of the instant application's failure to disclose, or claim, the subject matter presented in the claims of the '101 patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 44-53, 57-60, 62, 66-69, 71, 72, 74, 75, 77-80, 84, 86-89, 93-97, 99-102, 106 and 108-111 are rejected under 35 U.S.C. 102(e) as being anticipated by Avitall (5,263,493).

Avitall disclose a tissue ablation device for use the chambers of the heart. The device comprises an elongate member (18) adapted to be positioned adjacent to a circumferential region of tissue, and an ablation element (28) comprising a loop with a plurality of electrodes (36) that is adapted to form a lesion in a circumferential region of tissue. As seen in the figures, the ablation element is a loop (Figures 2 and 6) that is of a size and shape adapted to surround pulmonary veins in the atrium. The loop structure is collapsible (Figure 2B). Figure 4 shows an actuation element to control the shape and deployment of the ablation loop, and no fluid is delivered to tissue during the ablation procedure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54-56, 61, 63-65, 70, 81-83, 85, 90-92, 103-105, 107 and 112-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avitall ('493) in view of the teaching of Brucker et al (5,500,012).

The Avitall device has been addressed previously. Avitall disclose the use of individual electrodes to provide for mapping and thermal ablation of tissue. Avitall fail to disclose alternative energy means (i.e. laser, microwave, chemical) for ablation of cardiac tissue. It is noted that applicant's specification makes only a passing suggestion to the use of alternative ablative energy sources, and fails to disclose any of the particulars or show any of the specific arrangements for the various sources of energy. There is no criticality or unexpected result associated with any of the other mentioned energy sources, and applicant's specification shows and describes only RF electrode embodiments.

Brucker et al disclose another cardiac mapping and ablation catheter. The Brucker et al catheter discloses RF energy as the primary ablation energy, but also teaches that it is known to use alternative ablation energy modalities such as laser, microwave, ultrasonic and chemical fluids (col. 2, lines 53-55).

To have provided the Avitall ablation catheter with any well known ablation energy modality to create a lesion in cardiac tissue would have been an obvious consideration for one of ordinary skill in the art, particularly since Brucker et al teach of the known substitutability of the various well-known ablative energy sources in a cardiac ablation device.

Claims 73, 76 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avitall ('493) in view of the teaching of Webster, Jr (5,411,025).

Again, the Avitall reference has been addressed. Avitall provide an elongate member (18) with an ablation element (28) attached at the distal end thereof. However, Avitall fail to specifically disclose the use of a catheter through which the ablation element may be deployed into cardiac tissue.

Webster, Jr. discloses another cardiac mapping/ablation catheter that has a deployable ablation element at the distal end of a catheter. In particular, Webster, Jr. teach that it is advantageous to provide an outer sheath (8) through which the ablation member and elongate member may be deployed. The outer sheath allows the device to be inserted into the cardiac tissue prior to deployment of the ablation member.

To have provided the Avitall catheter with a deployment sheath to allow the ablation member to be concealed until it is located in proximity to the treatment tissue would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Webster, Jr.

Conclusion

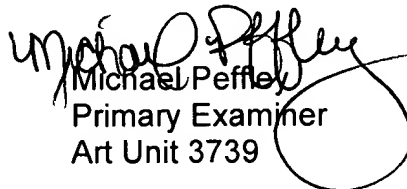
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kordis et al (5,636,634) and Edwards et al (5,293,869) disclose alternative mapping/ablation catheter systems that could be used to create circumferential lesions in cardiac tissue. Desai (4,940,064) discloses a cardiac ablation catheter with electrode elements that may be deployed to create a circumferential lesion.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
February 24, 2006


Dvorak TC 3200